# Exhibit A

# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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| THE COMMONWEALTH OF MASSACHUSETTS,       | )                                       |
| Plaintiff,                               | )                                       |
| v.                                       | ) CIVIL ACTION NO.<br>) 03-CV-11865-PBS |
| MYLAN LABORATORIES, INC., BARR           | )                                       |
| LABORATORIES, INC., DURAMED              | ) FIRST AMENDED                         |
| PHARMACEUTICALS, INC., IVAX CORPORATION, | ) COMPLAINT                             |
| WARRICK PHARMACEUTICALS CORPORATION,     | )                                       |
| WATSON PHARMACEUTICALS, INC., SCHEIN     | )                                       |
| PHARMACEUTICAL, INC., TEVA               | )                                       |
| PHARMACEUTICALS USA, INC., PAR           | )                                       |
| PHARMACEUTICAL, INC., DEY, INC., ETHEX   | )                                       |
| CORPORATION, PUREPAC PHARMACEUTICAL CO., | )                                       |
| and ROXANE LABORATORIES, INC.            | )                                       |
|  | )                                       |
| Defendants.                              | )                                       |
|  | )                                       |
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#### I. PRELIMINARY STATEMENT

1. Attorney General Thomas F. Reilly, on behalf of the Commonwealth of Massachusetts, brings this action against thirteen leading manufacturers of generic pharmaceutical products. This action alleges that the defendant manufacturers, over many years, by means of fraudulent promotional, marketing and sales practices, systematically and secretly have inflated the prices of generic pharmaceutical products paid for by the Massachusetts Medicaid program, resulting in millions of dollars in overpayments by the Commonwealth's taxpayers. Through these acts, each of these generic pharmaceutical manufacturers has violated the Massachusetts Medicaid False Claims Act and the Massachusetts False Claims Act and committed common law fraud.

Each of the defendant manufacturers has also breached the Medicaid Rebate Agreement through which it makes payments directly to the states, resulting in damages to the Commonwealth of Massachusetts. The Attorney General seeks injunctive relief, restitution, triple damages, civil penalties, attorneys' fees, and investigative and litigation costs.

# II. JURISDICTION AND VENUE

2. The Attorney General of the Commonwealth of Massachusetts is authorized to bring this action pursuant to M.G.L. c. 118E, §§ 44 and 45 and M.G.L. c. 12, §§ 5B, 5G and 10. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because the Commonwealth's claims under the Medicaid Rebate Agreements arise under federal law. This Court has supplemental jurisdiction over the Commonwealth's state law claims pursuant to 28 U.S.C. § 1367(a). The relief requested is authorized pursuant to M.G.L. c. 118E, § 44, M.G.L. c. 12, § 5B, 42 U.S.C. § 1396r-8 and the common law. Venue is proper pursuant to 28 U.S.C. § 1391(c).

#### III. PARTIES

#### **Plaintiff**

3. The Plaintiff Commonwealth of Massachusetts is a sovereign state and body politic duly organized by law, and is represented by the Attorney General of the Commonwealth, who brings this action in the public interest and on behalf of the Commonwealth and its citizens and taxpayers.

#### **Defendants**

- 4. Mylan Laboratories, Inc. ("Mylan") is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania.
- 5. Mylan is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Mylan and covered by Medicaid include, but are not limited to, phenytoin sodium extended, clozapine and lorazepam. The Mylan drugs and time periods that are the subject of this First Amended Complaint are listed in Exhibit AA Rev. 2, filed here with and incorporated here in.
- 6. Defendant Barr Laboratories, Inc. ("Barr") is a New York corporation with its principal place of business at 2 Quaker Road, Pomona, New York. Defendant Duramed Pharmaceuticals, Inc. ("Duramed") is a Delaware corporation with its principal place of business at 7155 East Kemper Road, Cincinnati, Ohio. On information and belief, Duramed is a whollyowned subsidiary of Barr.
- 7. Barr and Duramed are in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold by Barr and Duramed and covered by Medicaid include, but are not limited to, warfarin sodium, methotrexate sodium, naltrexone HCl and Apri. The Barr and Duramed drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit BB Rev. 2, filed herewith and incorporated herein.
- 8. Defendant Ivax Corporation ("Ivax") is a Florida corporation with its principal place of business at 4400 Biscayne Boulevard, Miami, Florida. Ivax is a subsidiary of Ivax

Industries, Inc., a Pennsylvania corporation with its principal place of business at Rock Plaza III, 101 Rock Road, Horsham, Pennsylvania.

- 9. Ivax is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Ivax and covered by Medicaid include, but are not limited to, clozapine, albuterol and baclofen. The Ivax drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit CC Rev. 2, filed herewith and incorporated herein.
- 10. Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a Delaware corporation with its principal place of business located at 1215 Moya Boulevard, Reno, Nevada. Warrick is a subsidiary of Schering-Plough Corporation, a New Jersey corporation with its principal place of business located in Kenilworth, New Jersey.
- 11. Warrick is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Warrick and covered by Medicaid include, but are not limited to, albuterol and albuterol sulfate. The Warrick drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit DD Rev. 2, filed here with and incorporated herein.
- 12. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Schein Pharmaceutical, Inc. ("Schein") is a Delaware corporation with its principal place of business at 100 Campus Drive, Florham Park, New Jersey. On information and belief, Schein is a whollyowned subsidiary of Watson.

- 13. Watson and Schein are in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold by Watson and Schein and covered by Medicaid include, but are not limited to, carisoprodol, hydrocodone with APAP, ibuprofen, Necon, lorazepam, labetalol HCl, trazodone HCl and methylphenidate HCl. The Watson and Schein drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit EE Rev. 2, filed herewith and incorporated here in.
- 14. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with its principal place of business at 650 Cathill Road, Sellersville, Pennsylvania. Teva is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Limited, a company organized under the laws of Israel with manufacturing sites in Israel, the U.S. and Europe, and an international marketing network.
- 15. Teva is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Teva and covered by Medicaid include, but are not limited to, cephalexin, clonazepam, naproxen, acetaminophen with codeine, carbamazepine, sulfamethoxazole/TMP and amiodarone HCl. The Teva drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit FF Rev. 2, filed here with and incorporated here in.
- 16. Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, New York. Par is a wholly-owned subsidiary of Pharmaceutical Resources, Inc., also a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, New York.

- 17. Par is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Par and covered by Medicaid include, but are not limited to, ranitidine HCl and ibuprofen. The Par drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit GG Rev. 2, filed here with and incorporated here in.
- 18. Dey, Inc. ("Dey") is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive, Napa California.
- 19. Dey is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Dey and covered by Medicaid include, but are not limited to, albuterol, albuterol sulfate, cromolyn sodium, ipratropium bromide and EpiPen. The Dey drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit HH Rev. 2, filed herewith and incorporated here in.
- 20. Ethex Corporation ("Ethex") is a Delaware corporation with its principal place of business at 10888 Metro Court, St. Louis, Missouri. Ethex is a wholly-owned subsidiary of KV Pharmaceutical Company ("KV"). KV is also a Delaware corporation with its principal place of business at 2503 South Hanley Road, St. Louis, Missouri.
- 21. Ethex is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Ethex and covered by Medicaid include, but are not limited to, NitroQuick, naproxen, hyoscyamine sulfate, oxycodone HCl and potassium chloride. The Ethex drugs and the time

periods that are the subject of this First Amended Complaint are listed in Exhibit II Rev. 2, filed herewith and incorporated herein.

- 22. Purepac Pharmaceutical Co. ("Purepac") is a Delaware corporation with its principal place of business at One Executive Drive, Fort Lee, New Jersey.
- 23. Purepac is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Purepac and covered by Medicaid include, but are not limited to, clonazepam, isosorbide mononitrate extended release and lorazepam. The Purepac drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit JJ Rev. 2, filed here with and incorporated herein.
- 24. Roxane Laboratories, Inc. ("Roxane") is a Delaware corporation with its principal place of business at Columbus, Ohio. On information and belief, Roxane is a subsidiary of Boehringer Ingelheim Corporation, a Nevada corporation with its principal place of business at 900 Ridgefield Road, Ridgefield, Connecticut.
- 25. Roxane is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold by Roxane and covered by Medicaid include, but are not limited to, ipratropium bromide, Roxicodone, Roxicet, azathioprine and lithium carbonate. The Roxane drugs and the time periods that are the subject of this First Amended Complaint are listed in Exhibit KK Rev. 2, filed herewith and incorporated herein.

#### IV. FACTS COMMON TO ALL CLAIMS

# Reimbursement for Prescription Products Under the Massachusetts Medicaid Program

- 26. The Massachusetts Medicaid program (the "Medicaid program") is a health care program administered by the Massachusetts Executive Office of Health and Human Services, Office of Medicaid ("Massachusetts Medicaid" or "MassHealth"), an agency of the Commonwealth of Massachusetts. Massachusetts Medicaid was formerly known as the Massachusetts Division of Medical Assistance ("DMA"). The Massachusetts Medicaid program is established pursuant to 42 U.S.C. §§ 1396 et seq. (the "Medicaid Statute"). Pursuant to the Medicaid Statute and the State plan for medical assistance approved by the United States Secretary of Health and Human Services (the "Secretary") and adopted by the Commonwealth, the United States participates in the funding for the Massachusetts program. The federal government provides approximately fifty percent of the funding for services provided under the Massachusetts State plan.
- 27. Among other medical services, the Medicaid program pays for certain prescription drugs provided to eligible low-income individuals, including people with disabilities, children and elder citizens. The Massachusetts Medicaid program currently spends approximately \$1 billion annually on pharmaceutical products.
- 28. Pursuant to federal and state regulations, reimbursement to medical providers for prescription drugs dispensed to participants in the Medicaid program is limited in accordance with formulas that are based on the provider's estimated acquisition cost of the drug or other regulatory limitations. In Massachusetts, the reimbursement rate for pharmacy providers for

multi-source drugs, including generic pharmaceuticals, is the lowest of: (a) the federal upper limit ("FUL") for the drug, if any, plus a dispensing fee; (b) the Massachusetts upper limit ("MULP") for the drug, if any, plus a dispensing fee; (c) the estimated acquisition cost of the drug, plus a dispensing fee; or (d) the pharmacy's usual and customary charge for the drug. 114.3 C.M.R. 31.04. Reimbursement for single-source pharmaceutical products, which are usually brand-name drugs, or in cases where a physician has requested (and Massachusetts Medicaid has approved) the dispensing of a non-generic multi-source drug, will not exceed the lower of (a) the estimated acquisition cost of the drug plus a dispensing fee, or (b) the usual and customary charge. *Id*.

29. 42 C.F.R. § 447.332 sets the procedure for establishing the FUL for multiple source drugs for which there are at least three sources. Under this regulation, the FUL is defined as

an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

Under the regulations setting the FUL, the limit is applied on an aggregate basis for all drugs reimbursed by the state's Medicaid program, and the states are therefore permitted to pay above the FUL for any particular drug.

30. Massachusetts regulations promulgated by the Massachusetts Division of Health Care Finance and Policy ("DHCFP," formerly the Rate Setting Commission) and Massachusetts Medicaid define estimated acquisition cost as an estimate of the price generally and currently paid by pharmacies for the most frequently purchased package size of a particular drug. 114.3 C.M.R. 31.02; 130 C.M.R. 406.402. Before August 3, 2002, estimated acquisition cost was further

defined by Massachusetts regulation as the drug wholesaler's acquisition cost ("WAC") plus 10%. 114.3 C.M.R. 31.02. Effective August 3, 2002, estimated acquisition cost is defined as WAC plus 6%. *Id.* Effective March 14, 2003, estimated acquisition cost is defined as WAC plus 5%. *Id.* 

#### The Defendant Manufacturers' Price Reporting Mechanisms

- submission of reports to drug pricing publishing services, what purports to be genuine pricing data for its products. This information is typically identified as the "Wholesale Acquisition Cost" ("WAC") and/or the "Average Wholesale Price" ("AWP") of particular products. At all times relevant to the Complaint, the defendant manufacturers have intended the WAC to be understood by the state Medicaid agencies as the average price paid by a wholesaler to a manufacturer for a given product. At all times relevant to the Complaint, the defendant manufacturers have intended the AWP to be understood by the state Medicaid agencies as being in the range of 15% to 20% above the average prevailing price charged by a drug wholesaler to its commercial customers for a given product. The drug pricing publishing services in turn compile, publish and distribute compendia of such pricing information for each defendant's products. The drug pricing publishing services purport not to investigate the accuracy of the information provided by the manufacturers, and disclaim responsibility for its accuracy.
- 32. At all times relevant to this action, each of the defendant manufacturers provided information on WAC prices and/or AWP prices for prescription drugs, or other drug pricing information, to First Data Bank ("FDB"), a data reporting service with its headquarters located in

San Bruno, California. At least one manufacturer, Warrick, published a "Direct Wholesale" price that it knew would be and was interpreted and published by FDB as the equivalent of WAC.

- charges its customers. On information and belief, each of the defendants uses undisclosed discounts, rebates and other inducements that have the effect of lowering the actual price charged to its customers. As a result of these concealed inducements, each defendant has prevented third parties, including the Commonwealth, from determining the true prices it actually charged its customers. At all times relevant to this action, each of the defendant manufacturers knew that information accurately reflecting the actual sales prices it charged its customers was not available to the state Medicaid agencies.
- 34. Each defendant knew and intended that the pricing information provided to the Commonwealth, both directly and indirectly, would be used by the Commonwealth to determine the reimbursement levels to be paid by Massachusetts Medicaid for that defendant's products.
- 35. At all times relevant to this action, neither Massachusetts Medicaid nor DHCFP knew the actual prices each of the defendants charged its customers for its products. Rather, Massachusetts Medicaid obtained pricing information from FDB, and Massachusetts Medicaid and DHCFP reasonably relied on this information in determining the Medicaid reimbursement levels for the products of each of the defendant manufacturers.

#### The Medicaid Rebate Program

36. Under the Omnibus Budget Reconciliation Act of 1990, Congress established a Medicaid Drug Rebate Program (the "Medicaid Rebate Program"). 42 U.S.C. § 1396r-8 (the "Rebate Statute"). The Medicaid rebate program provides that, in order for a manufacturer's

drugs to be eligible for reimbursement under Medicaid, the manufacturer is required to enter into either a national Medicaid Rebate Agreement ("Rebate Agreement") or, if authorized by the Secretary, a rebate agreement with a state directly. 42 U.S.C. § 1396r-8(a)(1). The Medicaid rebate program is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), for the benefit of the federal and state governments.

- 37. Under a Rebate Agreement, the manufacturer of a non-innovator generic drug is required to pay a rebate to each state in an amount equal to 11% of the Average Manufacturer Price ("AMP") of each unit of the generic drug for which the state Medicaid program paid reimbursement. 42 U.S.C. § 1396r-8(c)(3). For single source or innovator multiple source drugs, the rebate is the greater of 15.1% of the average manufacturer price ("AMP") or the difference between the AMP and manufacturer's "best price" for the drug. 42 U.S.C. § 1396r-8(c)(1). The AMP for a given drug, which is required to be reported to the Secretary by the manufacturer, is defined by statute as the average price paid to the manufacturer in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts, and must therefore reflect any other discounts, free goods, rebates and other inducements that have the effect of lowering the actual net price paid by customers to the manufacturer. 42 U.S.C. § 1396r-8 (k)(1).
- 38. The express and essential purpose of the Medicaid rebate program is to give the state Medicaid programs the benefit of the best price at which the manufacturer sells the drug to any public or private purchaser.

- 39. Pursuant to the Rebate Agreement and the Rebate Statute, AMPs are not reported to the states. See 42 U.S.C. § 1396r-8(b)(3)(A). Rather, each of the defendant manufacturers provides AMPs to CMS. CMS relies on the data provided by each of the defendant manufacturers to calculate the quarterly rebate amount for each unit of the defendants' covered drugs (the "Unit Rebate Amount" or "URA"). CMS provides the URAs for each covered drug to the state Medicaid agencies on a quarterly basis.
- 40. Under each manufacturer's Rebate Agreement and the Rebate Statute, both the Secretary and the state Medicaid agencies are required to keep confidential any pricing information disclosed by manufacturers or wholesalers in connection with their participation in the rebate program. See 42 U.S.C. § 1396r-8(b)(3)(D).
- 41. The Commonwealth of Massachusetts relies on the manufacturers' performance under the Rebate Agreements to obtain accurate URAs for covered drugs, and uses the information provided by CMS pursuant to the Rebate Agreements to calculate and submit rebate invoices to each of the defendant manufacturers.
- 42. Each defendant in this action has entered into a Rebate Agreement, and the products of each defendant are, as a result, eligible for reimbursement by the Commonwealth's Medicaid program. Each defendant participates in the Medicaid Rebate Program and is subject to all the legal duties imposed upon it pursuant to the statutory and regulatory authority governing the Medicaid Rebate Program.
- 43. The Commonwealth of Massachusetts relied on the benefits conferred by the Medicaid Rebate Program, and on the performance by each of the defendant manufacturers of the

obligations imposed by the Rebate Agreements, to ensure that the Massachusetts Medicaid program paid the best price available for the pharmaceutical products of each of the defendants.

# The Defendants' Reported WACs, AWPs and Other Reported Pricing Data Were False and Fraudulent

- 44. On information and belief, the WAC, AWP and other prices reported by each of the defendants directly and indirectly to the Commonwealth do not reflect, and have no correlation to, the actual prices charged to customers for pharmaceutical products in the market. Rather, these reported WAC, AWP and other prices are materially inflated.
- 45. On information and belief, in those instances in which the defendant manufacturers reported false and inflated WACs to First Data Bank, FDB (a) provided the Massachusetts Medicaid program with the false and inflated WACs; or (b) derived WAC-based calculations of Estimated Acquisition Cost (WAC plus 10% or WAC plus 6%, depending upon the rate in effect at the time of the report) for the manufacturers' drugs and provided them to Massachusetts Medicaid. On information and belief, the pricing information that FDB provided to Massachusetts Medicaid was based upon the manufacturers' false and inflated WACs.
- 46. On information and belief, in those instances in which the defendant manufacturers did not report WACs to First Data Bank, they reported false and inflated AWPs and/or "direct" prices to FDB. FDB in turn (a) provided Massachusetts Medicaid with the false and inflated AWPs, from which Massachusetts Medicaid derived WAC-based calculations of Estimated Acquisition Cost (WAC plus 10% or WAC plus 6%, depending upon the rate in effect at the time of the report) for the manufacturers' drugs; or (b) derived WAC-based calculations of Estimated Acquisition Cost for the manufacturers' drugs using the false and inflated AWP or direct prices

submitted by the manufacturer as detailed below and provided those values to Massachusetts Medicaid.

- 47. As a direct result of these false and inflated reports of WACs, AWPs and other pricing data, where a federal FUL was established, it was set at an amount far higher than the amount that would have been set if any manufacturer of a particular product published an accurate WAC, AWP or other pricing data. Both as a result of this effect on the inflation of the FULs and as a result of the effect of these false and inflated WACs, AWPs and other reported pricing data on Massachus etts Medicaid's reimbursement formulas, Massachus etts Medicaid paid pharmacy providers excessive amounts for pharmaceutical products.
- 48. At all times relevant to this action, each of the defendant manufacturers knew that the published WACs, AWPs and other reported pricing data it had provided for its products failed to reflect accurately the actual sales prices paid by its customers.
- 49. At all times relevant to this action, each of the defendant manufacturers knew that the Medicaid reimbursement levels for its products were based upon these improperly inflated WACs, AWPs and other reported pricing data.
- 50. In falsely and fraudulently inflating its reported prices, each defendant knowingly and intentionally subverted the Medicaid provider cost-reimbursement system so that each defendant caused the Medicaid reimbursement materially to exceed the providers' acquisition cost of that defendant's drugs.
- 51. The intention of each of the defendant manufacturers in providing false and misleading pricing information for publication was to create a spread between the published prices for its products, upon which government reimbursement rates are based, and the actual prices

paid by its customers. The purpose of each defendant in creating the spread was to provide incentives or kickbacks for customers who buy and distribute its products, to increase the profits for such customers at the expense of the state Medicaid programs, and to increase its own profits by increasing its market share for particular drugs and classes of drugs.

- 52. Notwithstanding the pricing data that each defendant provided directly and indirectly to the Commonwealth, each defendant reported to CMS or HCFA, on a quarterly basis, AMPs that were materially lower than its reported WACs, AWPs and other prices, and these lower AMPs were used by CMS or HCFA in determining the URAs upon which each defendant's rebates to the state Medicaid programs were based.
- relevant to the complaint and beginning at least as early as 1994. Exhibits AA through KK Rev. 2 to the First Amended Complaint, filed under seal, set forth the following data for each relevant quarter for each of the drugs of each defendant that are the subject of this First Amended Complaint: (a) "Calc. AMP +10%" and "AMP + 6%": the calculated AMP + 10% or AMP + 6% as applicable under the Massachusetts Medicaid reimbursement formula then in effect; (b) "WAC + 10%," "WAC" and "AWP": the WAC + 10%, WACs and AWPs reported to Massachusetts Medicaid by First DataBank; (c) "FUL": the applicable Federal Upper Limit if any; (d) "Reimb. Per Unit": the amount that Massachusetts Medicaid reimbursed for each unit of the drug during the quarter; (e) "Total Units": the total number of units for which the Massachusetts Medicaid program paid reimbursement; (f) "Net Reimb.": the amount reimbursed by the Massachusetts Medicaid program net of any dispensing fees; (g) "Total Rxs": the total number of prescriptions; (h) "Total Reimb.": the total amount reimbursed by the Massachusetts

Medicaid program, including dispensing fees, for the prescriptions reimbursed during the quarter, (i) "Fee": the applicable dispensing fee per prescription; and (j) "Total Fees": the total paid in dispensing fees for the drug during the quarter. The net reimbursement amount for each drug has been determined by multiplying the applicable dispensing fee for each quarter by the total number of prescriptions filled and subtracting that amount, the "Total Fees," from the Total Reimbursement by the Mass achusetts Medicaid program for the drug. This reimbursement amount net of dispensing fees is divided by the total number of units reimbursed to arrive at the reimbursement amount per unit. With the service of the complaint, each defendant has been provided with a copy of that portion of Exhibits AA through KK Rev. 2 pertaining solely to its products.

- 54. On information and belief, for those quarters in which there are zeros shown in the "Cakulated AMP + 10% column for any particular drug, the defendant has failed timely to report its AMP to CMS in violation of the rebate agreement. Each of these drugs and quarters are accordingly the subject of Count VII.
- 55. The Warrick drugs and Roxane's Ipratropium Bromide are reported to CMS as innovator multiple source drugs. Accordingly, it was not always possible without discovery to determine from the URAs CMS provided to the states what Warrick and Roxane reported to CMS as AMPs for these drugs. It is possible to determine the maximum AMP that Warrick and Roxane could have reported based upon the URAs reported by CMS. For the Warrick drugs and Roxane's Ipratropium Bromide, this maximum has been provided where the actual AMP is unavailable to the Commonwealth.

- 56. Allegations relating to defendant Mylan and its drugs that are the subject of this First Amended Complaint are contained in Exhibit AA Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Mylan in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit AA Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Mylan reported a change to FDB as reflected in Exhibit AA Rev. 2. For Phenytoin Sodium, NDC # 00378156001 at page 7 of Exhibit AA Rev. 2, the Commonwealth's current records do not list the WAC+10% that was reported for 1999. However, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the Commonwealth believes and therefore alleges that the reported WAC+10% was the same as reported for 2000. CMS has not reported a URA from which the AMP can be derived for Phenytoin Sodium, NDC ## 00378156001 and 00378156010 at pages 7 and 8 of Exhibit AA Rev. 2 for the third quarter of 2002. On information and belief, Mylan has failed to report timely the AMP for this period for this drug in violation of the Rebate Agreement that requires that the AMP and best price be reported within thirty days following the end of a quarter.
- 57. Allegations relating to defendants Barr and Duramed and their drugs that are the subject of this First Amended Complaint are contained in Exhibit BB Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs

provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Barr or Duramed in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit BB Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until either Barr or Duramed reported a change to FDB with regard to its drug as reflected in Exhibit BB Rev. 2.

58. Allegations relating to defendant Ivax and its drugs that are the subject of this First Amended Complaint are contained in Exhibit CC Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Ivax in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit CC Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Ivax reported a change to FDB with regard to its drug as reflected in Exhibit CC Rev. 2. For Baclofen, NDC # 00172409660 at page 1 of Exhibit CC Rev. 2, the Commonwealth's current records do not list the WAC that was reported for the second quarter of 1994 through the first quarter of 1996. However, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the Commonwealth believes and therefore alleges that the reported WAC+10% for the period prior to the second quarter of 1996 is at least as high as the unit reimbursement amount for those periods.

The same is true for the first quarter of 1996 through the third quarter of 1997 for albuterol, NDC # 00172439018 at page 7 of Exhibit CC Rev. 2. The Commonwealth believes and alleges that the reported WAC+10% was the same as for the fourth quarter of 1997. CMS has not reported a URA from which the AMP can be derived for Clozapine, NDC ## 00172435970, 00172436060, 00172436070 and 00172435960 for the periods fourth quarter 1997 through the fourth quarter 1999 and for the second quarter of 2000, or for albuterol, NDC ## 00172439018 and 9019 for the periods third quarter of 1996 through first quarter of 1997 and second quarter of 2002 through the fourth quarter of 2002 for 9019. On information and belief, Ivax has failed timely to report the AMP for these periods in violation of the rebate agreement that requires that the AMP and best price be reported within thirty days following the end of a quarter.

First Amended Complaint are contained in Exhibit DD Rev. 2. The Warrick drugs are reported to CMS as innovator multiple source drugs. Accordingly, for Albuterol Sulfate, NDC # 59930150008 at page 1 of Exhibit DD Rev. 2 for the third quarter of 1994 through the first quarter of 1995 and for the second quarter of 2000 through the second quarter of 2002, it was not possible without discovery to determine from information provided by CMS to the states what Warrick reported to CMS as AMPs for this drug during these periods. The "AMP + 10%" shown on the schedule is the maximum that could have been reported for these periods based on the URAs reported to the Commonwealth. On information and belief, based on the actual AMPs that are available for other contiguous periods, the actual AMP's for these periods are consistent with the actual AMPs for other periods. The same is true for Albuterol Sulfate, NDC # 59930151504 at page 3 of Exhibit DD Rev. 2 for the first quarter of 1995 and the second quarter of 2000

through the first quarter of 2003 and for Albuterol, NDC # 59930156001 at page 5 of Exhibit DD Rev. 2 for the first quarter of 1996 through the third quarter of 1996 and the second quarter of 2000 through the first quarter of 2003. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, Warrick reported to FDB and the Commonwealth both an AWP and a "Direct Wholesale" price. Warrick knew and expected that the Direct Wholesale price would be interpreted by FDB as the equivalent of WAC and reported to the Commonwealth as WAC. Warrick reported the Direct Wholesale price to the Commonwealth "for reimbursement purposes." On information and belief, the Direct Wholesale and AWP prices were first reported to FDB when the products were first introduced or in or about the time that they were first reported to the Commonwealth as reflected in Exhibit DD Rev.

2. Once published, the WAC for a particular drug remained the same until Warrick reported a change in the Direct Wholesale price to FDB as reflected in Exhibit DD Rev. 2.

Allegations relating to defendants Watson and Schein and their drugs that are the subject of this First Amended Complaint are contained in Exhibit EE Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Watson or Schein as applicable in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit EE. Once published, the WAC and AWP for a particular drug remained the same until Watson or Schein reported a change to FDB as reflected in Exhibit EE Rev. 2. For Watson Necon, NDC # 52544055228 at page 7 of the Watson section of Exhibit EE Rev. 2, the

Commonwealth's current records do not list the WAC + 10% that was reported for the second quarter of 1997 through the first quarter of 1998. However, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the Commonwealth believes and therefore alleges that the reported WAC+10% was the same as reported for the following contiguous quarters. The same is true for Schein Carisoprodol, NDC # 00364047505 at page 3 of the Schein portion of the Exhibit EE for the second quarter of 1993 and fourth quarter of 1994, for Schein Methylphenidate HCL, NDC # 00364047901 at page 4 of the Schein portion of the Exhibit EE for the third quarter of 1994 through the third quarter of 1995, and for Schein Methylphenidate HCL, NDC # 00364056101 at page 7 of the Schein portion of the Exhibit EE for the second quarter of 1994 through the third quarter of 1995.

61. Allegations relating to defendant Teva and its drugs that are the subject of this

First Amended Complaint are contained in Exhibit FF Rev. 2. The "AMP+10%" and "AMP+6%"
figures shown in the columns with these titles were derived from the URAs provided to the

Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to
the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to
FDB by Teva in or about the time that the products were first introduced or they were first
reported to the Commonwealth by FDB as listed in Exhibit FF Rev. 2. Once published, the WAC
and AWP for a particular drug remained the same until Teva reported a change to FDB as
reflected in Exhibit FF Rev. 2. For Clonazepam, NDC # 00093083201 at page 15 of Exhibit FF
Rev. 2, the Commonwealth's current records do not list the WAC + 10% that was reported
during the fourth quarter of 1996 through the second quarter of 1998. However, the

Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels as shown on the schedule, the Commonwealth believes and therefore alleges that the reported WAC+10% was approximately the same as the reimbursement levels. The same is true for Clonazepam, NDC ## 00093083301 and 00093083401 at pages 16 and 17 respectively of Exhibit FF Rev. 2 for the fourth quarter of 1996 through the second quarter of 1998.

- Allegations relating to defendant Par and its drugs that are the subject of this First Amended Complaint are contained in Exhibit GG Rev. 2. The "AMP+10%" and "AMP+6%" figures sho wn in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, FDB derived the WAC and WAC+10% amounts from false and inflated AWPs provided to FDB by Par. On information and belief, FDB derived the WACs by multiplying the AWP by an industry standard fraction of approximately 80%. On information and belief, the false and inflated AWPs were provided to FDB by Par in or about the time that the products were first introduced or each WAC+10% figure was first reported to the Commonwealth by FDB as listed in Exhibit GG Rev. 2. Once published, the WAC + 10% for a particular drug remained the same until Par reported a change in the AWP to FDB as reflected in Exhibit GG Rev. 2.
- 63. Allegations relating to defendant Dey and its drugs that are the subject of this First Amended Complaint are contained in Exhibit HH Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to

the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Dey in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit HH Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Dey reported a change to FDB as reflected in Exhibit HH Rev. 2. For the periods second quarter of 1998 through the first quarter of 1999 for Epipen, NDC # 49502050001, and Epipen Jr, NDC # 49502050101 at pages 1 and 2 respectively of Exhibit HH Rev. 2, the Commonwealth's current records do not list the WAC + 10% that was reported. However, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the Commonwealth believes and therefore alleges that the reported WAC+10% was approximately the same as those reported for the subsequent contiguous quarters. The same is true the first through fourth quarters of 1997 for Ipratropium Bromide, NDC ## 49502068503 and 49502068560 at pages 3 and 5 respectively of Exhibit HH Rev. 2, for Cromolyn Sodium, NDC ## 49502068902 and 49502068912 at pages 6 and 8 respectively of Exhibit HH Rev. 2 for the periods third quarter 1994 through the fourth quarter of 1997, and for Albuterol Sulfate, NDC ## 49502069703, 49502069733, 49502069760 and 49502030317 at pages 10, 12, 13 and 14 respectively of Exhibit HH Rev. 2 for the periods for which there is no number listed on the schedule.

64. Allegations relating to defend ant Ethex and its drugs that are the subject of this First Amended Complaint are contained in Exhibit II Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to

the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Ethex in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit II Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Ethex reported a change to FDB as reflected in Exhibit II Rev. 2. For the periods prior to the first quarter of 2000 for Potassium Chloride, NDC ## 58177000104, 58177000108, and 58177000109 at pages 1, 3 and 5 respectively of Exhibit II Rev. 2, the Commonwealth's current records do not list the WAC + 10% that was reported. Ho wever, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the fact that there were no applicable FULs and the pattern of reporting for other time periods and drugs, the Commonwealth believes and therefore alleges that the reported WAC+10% was approximately the same as the Commonwealth's reimbursement for the equivalent periods.

Allegations relating to defend ant Purepac and its drugs that are the subject of this First Amended Complaint are contained in Exhibit JJ Rev. 2. The "AMP+10%" and "AMP+6%" figures sho wn in the columns with these titles were derived from the URAs provided to the Commonwealth by CMS. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the WACs and AWPs were provided to FDB by Purepac in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit JJ Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Purepac reported a change to FDB as reflected in Exhibit JJ Rev. 2. For the two quarters prior to the fourth quarter of 1997 for

Clonazepam, NDC # 00228300311 at page 7 and for the second quarter of 1997 for Clonazepam, NDC # 00228300411 at page 9 of Exhibit II Rev. 2, the Commonwealth's current records do not list the WAC + 10% that was reported. However, the Commonwealth would not have been able to make reimbursement for the drug unless it had been provided the WAC or WAC+10% by FDB. Based on the reimbursement levels, the fact that there were no applicable FULs and the pattern of reporting for other time periods and drugs, the Commonwealth believes and therefore alleges that the reported WAC+10% was approximately the same as the Commonwealth's reimbursement for the equivalent periods.

Allegations relating to defendant Rox ane and its drugs that are the subject of this First Amended Complaint are contained in Exhibit KK Rev. 2. The "AMP+10%" and "AMP+6%" figures shown in the columns with these titles for all drugs except Ipratropium Bromide were derived from the URAs provided to the Commonwealth by CMS. The Roxane Ipratropium Bromide is reported to CMS as an innovator multiple source drug. Accordingly, for Ipratropium Bromide, NDC # 00054840211 at page 8 of Exhibit KK Rev. 2 for the first quarter of 1997 through the first quarter of 1998 and for the fourth quarter of 2000 through the first quarter of 2003 it was not possible without discovery to determine from information provided by CMS to the states what Roxane reported to CMS as AMPs for this drug during these periods. The "AMP + 10%" shown on the schedule for these periods is the maximum that could have been reported based on the URAs reported to the Commonwealth. On information and belief, based on the actual AMPs that are available for other contiguous periods, the actual AMP's for these periods are consistent with the actual AMPs for other periods. The WAC+10%, WAC and AWP figures are the amounts provided to the Commonwealth by FDB. On information and belief, the

WACs and AWPs were provided to FDB by Roxane in or about the time that the products were first introduced or they were first reported to the Commonwealth by FDB as listed in Exhibit KK Rev. 2. Once published, the WAC and AWP for a particular drug remained the same until Roxane reported a change to FDB as reflected in Exhibit KK Rev. 2.

67. As reflected in Exhibits AA Rev. 2 through KK Rev. 2, the AMPs reported by each defendant manufacturer to CMS or HCFA for each of the subject drugs and applicable periods are materially lower than the Medicaid reimbursement amounts for those products.

#### COUNT I

#### Fraud

- 68. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through sixty-seven (1-67) above, as if they were fully set forth here.
- 69. Each of the defendants knew that its promotional, marketing and sales practices employed false and misleading pricing information provided to the national drug price reporting services.
- 70. Each of the defendants intended to induce the Commonwealth of Massachusetts, through Massachusetts Medicaid and the DHCFP, to rely upon the statements and representations contained in this false and misleading pricing information.
- 71. The Commonwealth did in fact reasonably rely upon the statements and representations contained in this false and misleading pricing information.
- 72. As a result of its reasonable reliance upon the statements and representations contained in this false and misleading pricing information, the Commonwealth of Massachusetts

paid its Medicaid pharmacy providers sums in excess of the amounts the providers should have received.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### COUNT II

#### **Unjust Enrichment**

- 73. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through seventy-two (1-72) above, as if they were fully set forth here.
- 74. As a result of the statements and representations contained in each defendant's false and misleading pricing information, the Commonwealth of Massachusetts paid its Medicaid pharmacy providers sums in excess of the amounts to which the providers were entitled.
- 75. Each defendant knew that the Commonwealth's Medicaid providers were not entitled to these improperly inflated reimbursements.
- 76. As a result of the Commonwealth's excessive payments to its Medicaid pharmacy providers, each of the defendants obtained increased sales and market share and was unjustly enriched at the expense of the Commonwealth of Massachusetts.
- 77. Each defendant knew that it was not entitled to the profits it realized from the increased sales and increased market share that resulted from the Commonwealth's excessive payments to its Medicaid pharmacy providers.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### COUNT III

#### Violations of the Massachusetts Medicaid False Claims Act

#### (M.G.L. c. 118E, §§ 40 and 41)

- 78. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through seventy-seven (1-77) above, as if they were fully set forth here.
- 79. Each of the defendants produces, markets and sells pharmaceutical products for which Massachusetts Medicaid makes payment.
- 80. Each of the defendants knowingly and wilfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to Massachusetts Medicaid, to obtain reimbursement for Medicaid providers for its pharmaceutical products, in violation of M.G.L. c. 118E, § 40.
- 81. Each of the defendants uses devices and schemes that have the effect of increasing the total amount claimed or paid for its pharmaceutical products and services beyond the maximum allowable amount payable for such products and services under the applicable rate or fee schedule, in violation of M.G.L. c. 118E, § 40.
- 82. The failure of each of the defendants to disclose to governmental entities or to the drug pricing reporting services the marketing, promotional and pricing inducements it offers to its purchasers, and the failure of each of the defendants to report the net reduction in the prices paid by the purchasers of its products caused by these inducements, constitute violations of M.G.L. c. 118E, § 40.

- 83. The conduct of each of the defendants in providing discounts, rebates and other price-based incentives to its customers, with the intention that these inducements increase the profits for such purchasers at the expense of the Massachusetts Medicaid program, constitutes an illegal kickback in violation of M.G.L. c. 118E, § 41.
- 84. The conduct of each of the defendants in manipulating reimbursement levels so as to preclude the Massachusetts Medicaid program from benefitting from these inducements, constitutes the provision of an illegal kickback in violation of M.G.L. c. 118E, § 41.
- 85. As a result of these false statements and/or representations of material facts by each of the defendants, Massachusetts Medicaid has paid sums in excess of the amounts that should have been paid to Medicaid providers for pharmaceutical products.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### **COUNT IV**

#### Violations of the Massachusetts False Claims Act

#### (M.G.L. c. 12, §§ 5A et seq.)

- 86. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through eighty-five (1-85) above, as if they were fully set forth here.
- 87. Each of the defendants produces, markets and sells pharmaceutical products for which Massachusetts Medicaid makes payment.
- 88. Each of the defendants knowingly and wilfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to Massachusetts

Medicaid, to obtain reimbursement for Medicaid providers for its pharmaceutical products, in violation of M.G.L. c. 12, §§ 5A et seq.

- 89. Each of the defendants uses devices and schemes that have the effect of increasing the total amount claimed or paid for pharmaceutical products and services beyond the maximum allowable amount payable for such products and services under the applicable rate or fee schedule, in violation of M.G.L. c. 12, §§ 5A et seq.
- 90. The failure of each of the defendants to disclose to governmental entities or to the drug pricing reporting services the marketing, promotional and pricing inducements it offers to its purchasers, and the failure of each of the defendants to report the net reduction in the prices paid by the purchasers of its products caused by these inducements, constitute violations of M.G.L. c. 12, §§ 5A et seq.
- 91. As a result of these false statements and/or representations of material facts by each of the defendants, Massachusetts Medicaid has paid sums in excess of the amounts which should have been charged for pharmaceutical products.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### COUNT V

#### Breach of Contract - Under-reporting of AMPs

92. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through ninety-one (1-91) above, as if they were fully set forth here.

- 93. Pursuant to 42 U.S.C. § 1396r-8, each of the defendants has entered into a Rebate Agreement, under which each defendant agreed to provide to CMS or HCFA periodic reports of true and accurate pricing information concerning sales of its pharmaceutical products in the form of an AMP as defined in the Rebate Statute, and to pay the Commonwealth a rebate for each unit of its covered drugs reimbursed by the Commonwealth under the Medicaid program.
- 94. The Commonwealth of Massachusetts is a party to or an intended third-party beneficiary of the Rebate Agreements entered into by each of the defendants.
- 95. Based on the pricing information that each defendant provided to the Commonwealth, both directly and indirectly through national pricing data reporting services, the AMPs reported by each defendant for purposes of calculating the rebates due under the Rebate Agreements were materially understated.
- 96. In materially understating its AMPs, each defendant has breached its Rebate Agreement.
- 97. Each defendant, as a result of its failure to comply with its obligations under its Rebate Agreement, has deprived the Commonwealth of Massachusetts of the appropriate level of rebates for covered pharmaceutical products as provided in the Rebate Agreements and as mandated by 42 U.S.C. § 1396r-8.
- 98. The Commonwealth has been damaged in an amount equal to the difference between the rebates that should have been paid and the rebates actually paid by each defendant.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### COUNT VI

### Breach of Contract: Breach of Duty of Good Faith and Fair Dealing

- 99. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through ninety-eight (1-98) above, as if they were fully set forth here.
- 100. Pursuant to 42 U.S.C. § 1396r-8, each defendant has entered into a Rebate

  Agreement, under which it agreed to pay the Commonwealth a rebate for each unit of its covered drugs reimbursed by the Commonwealth under its Medicaid program.
- 101. The Commonwealth of Massachusetts is party to or an intended third-party beneficiary of the Rebate Agreements entered into by each of the defendants.
- 102. The essential purpose and intent of the Rebate Agreements is to ensure that the state Medicaid programs pay the lowest price available in the market for the participating manufacturers' pharmaceutical products.
- 103. Notwithstanding each defendant's obligations under its Rebate Agreement to pay rebates to the Commonwealth in such amounts as will cause the Medicaid program to pay the lowest price available in the market for the participating manufacturers' pharmaceutical products, each defendant has deprived the Commonwealth of the full benefit of the Rebate Agreement by reporting false and inflated pricing data for its drugs. These reports of false and inflated pricing information caused the reimbursement rates for each defendant's drugs to be artificially inflated in amounts materially in excess of any rebates paid under that manufacturer's Rebate Agreement. Each defendant has thereby frustrated the fundamental purpose and intent of its Rebate Agreement and deprived the Commonwealth of the full benefits of that Agreement.

104. In so doing, each defendant has breached its duty of good faith and fair dealing implicit in its Rebate Agreement, and the Commonwealth has been damaged in the amount that it was caused to overpay for each defendant's drugs.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### COUNT VII

#### Breach of Contract - Failure to Report AMP Timely

- 105. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through one hundred five (1-105) above, as if they were fully set forth here.
- Agreement, under which it agreed to pay the Commonwealth rebates as defined in the Rebate Agreement for each unit of its covered drugs reimbursed by the Commonwealth under its Medicaid program. Pursuant to Section II.(e) of the Rebate Agreement, each manufacturer is required, within 30 days following the last day of each quarter, to report to CMS the Average Manufacturer Price ("AMP") for each covered drug. CMS then uses the AMP to calculate the Unit Rebate Amount ("URA") for each such drug and reports the URA for each such drug to the states.
- 107. The Commonwealth of Massachusetts is party to or an intended third-party beneficiary of the Rebate Agreements entered into by each of the defendants.
- 108. Notwithstanding each defendant's obligations under its Rebate Agreement to report the AMP to CMS within 30 days following the end of the quarter, on information and

belief each defendant has failed to do so for the quarters in which the Calculated AMP + 10% is listed as "\$0.00000" on the Exhibit AA to KK applicable to that defendant.

109. By failing to report the AMP's timely, each such defendant has breached its Rebate Agreement, and the Commonwealth has been damaged thereby in an amount to be proved at trial.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### PRAYER FOR RELIEF

Based on the foregoing, the Commonwealth of Massachusetts respectfully demands judgment as follows:

- A. An order of this Honorable Court enjoining each of the defendants from engaging in practices that violate M.G.L. c. 118E, §§ 40 and 41, M.G.L. c. 12, §§ 5A et seq., 42 U.S.C. § 1396r-8 and their obligations under the Medicaid Rebate Agreement;
  - B. Damages in such amount as is proved at trial;
  - C. Damages trebled pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
  - D. Disgorgement of all excessive profits in such amount as is proved at trial;
  - E. Civil penalties pursuant to M.G.L. c. 12, § 5B;
- F. Reimbursement for all investigative and litigation costs, including experts' fees, pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
  - G. An award of attorneys' fees pursuant to M.G.L. c. 12, § 5B; and
  - H. Such other and further relief as this Honorable Court deems proper and just.

### JURY DEMAND

The Commonwealth of Massachusetts demands trial by jury on all claims so triable.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS

By its attorney,

THOMAS F. REILLY Attorney General

/s/ Richard C. Heidlage By:

> Nicholas J. Messuri (BBO# 547144) David R. Marks (BBO# 548982) Robert Patten (BBO# 555287) Richard C. Heidlage (BBO# 228940) Bruce F. Anderson (BBO# 658750)

Assistant Attorneys General

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May 19, 2005

(617) 727-2200

#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 19th day of May, 2005, I caused to be served, by first class mail, postage prepaid, on each counsel of record for each defendant a true copy of that portion of Exhibits AA through KK Rev. 2 pertaining to the defendant represented by that counsel.

/s/ Richard C. Heidlage